BIOMET SPINE

510(k) Summary

This summary of 510(k) safety and effectiveness information is being submitted in accordance with the requirements of 21 CFR § 807.92.

Preparation Date:	May 31, 2013
Applicant/Sponsor:	Biomet Spine 399 Jefferson Road Parsippany, NJ 07054
Contact Person:	Vivian Kelly Regulatory Affairs Project Manager Phone: 973-299-9300 x2214 Fax: 973-887-1347
Trade name:	Polaris Spinal System
Common Name:	Non-cervical spinal fixation system
Classification Name (Product Code):	Posterior, noncervical, nonpedicle use (KWP) Anterior/anterolateral noncervical use (KWQ) Noncervical pedicle applications (MNI, MNH and NKB) Pedicle screw spinal system, adolescent idiopathic scoliosis (OSH)
Device Panel - Regulation No.:	Orthopedic - 21 CFR 888.3050, 888.3060 and 888.3070

SEP 04 2013

Device Description:

The Polaris Spinal System is a non-cervical spinal fixation device made from titanium alloy (Ti-6Al-4V) per ASTM F 136, unalloyed titanium per ASTM F 67, stainless steel per ASTM F 138 or ASTM F 1314 and Cobalt Chrome Alloy (Co-28Cr-6Mo) per ASTM 1537. The system includes screws, various types and sizes of rods, locking nuts, hooks, lateral connectors, plugs, fixation washers, rod connectors/dominos and various cross connectors. Various instruments are also available for use by the surgeon to facilitate implantation of the device. This line extension is to expand the indications for use for Polaris Spinal System using previous cleared system components.

Indications for Use:

The Polaris Spinal System is a non-cervical spinal fixation device intended for immobilization and stabilization as an adjunct to fusion as a pedicle screw fixation system, a posterior hook and sacral/iliac screw fixation system, or as an anterior or anterolateral fixation system for use with autograft and/or allograft. The Polaris Spinal System is indicated for the following conditions: degenerative disc disease (defined as discogenic back pain with degeneration of the disc confirmed by history and radiographic studies), spondylolisthesis, trauma, (i.e., fracture or dislocation), deformity or curvature (i.e., scoliosis, kyphosis, Scheuermann's disease, and/or lordosis,), tumor, stenosis, pseudoarthrosis, or failed previous fusion.

The Ballista/Ballista II instruments are intended to be used with Ballista/Balllista II/Polaris 5.5mm implants. Cannulated screws and percutaneous rods may be used with the Ballista/Ballista II instruments to provide the surgeon with a percutaneous approach for posterior spinal surgery for the above indications.

For pediatric patients, the Polaris Spinal System may be used for posterior, non-cervical pedicle screw fixation as an adjunct to fusion to treat adolescent idiopathic scoliosis and is also indicated for treatment of the following conditions: spondylolisthesis/spondylolysis and fractures caused by tumor and/or trauma. Pedicle screw fixation is limited to a posterior approach.

The Polaris Spinal System may be used with the instruments in the AccuVision Minimally Invasive Spinal Exposure System to provide the surgeon with a minimally invasive approach for posterior spinal surgery.

The dominos in the Polaris Spinal System can be used to connect the Polaris Spinal System to the Altius Spinal System, Nextgen Altius OCT Spine System, The Array Spinal System, the Biomet Omega21 Spinal System, or the Synergy Spinal System to achieve additional levels of fixation. Please refer to the individual system's Package Insert for a list of the indications for use for each system.

Summary of Technologies:

The technological characteristics of the Polaris Spinal System remain the same as, or similar to, the predicate devices in regards to intended use, indications, design, materials, manufacturing methods, sterility, fundamental technology, and operational principles.

Performance Data:

The implants included in the submission were previously tested for static compression bending, static torsion and dynamic compression bending per ASTM F1717. Because the system's mechanical strength has already been demonstrated, additional testing is not required to demonstrate substantial equivalence for expanded indications and an engineering rationale was provided.

To support substantial equivalence, a clinical literature assessment was conducted using published clinical data for pedicle screw fixation for adolescent idiopathic scoliosis. The assessment concluded that pedicle screw fixation is safe and effective for use in pediatric patients for the treatment of adolescent idiopathic scoliosis.

Substantial Equivalence:

The Polaris Spinal System is substantially equivalent to the Revere® 4.5 Stabilization System, Globus Medical Inc. (K113395), the CD Horizon® Spinal System, Medtronic (K091445, K111457 & K113395) and the TSRH® Spinal System, Medtronic (K110070) for pediatric pedicle screw use and the Polaris Spinal System (K123549 & K090203) in regards to material, design and operational principles.

Conclusion:

The Polaris Spinal System is substantially equivalent to the predicate systems as spinal fixation devices in regards intended use, indications, design, materials, manufacturing methods, sterility, fundamental technology, and operational principles. Furthermore, preclinical data, the clinical literature assessment review and other supporting information sufficiently demonstrate the substantial equivalence of the subject device to the Polaris Spinal System and the other named predicate systems, which have been cleared for pedicle screw fixation for adolescent idiopathic scoliosis, Scheuermann's Disease, and spondylolysis.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Center – WO66-G609
Silver Spring, MD 20993-0002

September 4, 2013

Biomet Spine
Ms. Vivian Kelly
Regulatory Affairs Project Manager
399 Jefferson Road
Parsippany, New Jersey 07054

Re: K131615
Trade/Device Name: Polaris Spinal System
Regulation Number: 21 CFR 888.3070
Regulation Name: Pedicle screw spinal system
Regulatory Class: Class III
Product Code: NKB, OSH, MNI, MNH, KWP, KWQ
Dated: August 12, 2013
Received: August 15, 2013

Dear Ms. Kelly:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you; however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set

forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

Mark N. Melkerson -S

Mark N. Melkerson
Director
Division of Orthopedic Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Indications for Use

510(k) Number (if known): K131615

Device Name: Polaris Spinal System

The Polaris Spinal System is a non-cervical spinal fixation device intended for immobilization and stabilization as an adjunct to fusion as a pedicle screw fixation system, a posterior hook and sacral/iliac screw fixation system, or as an anterior or anterolateral fixation system for use with autograft and/or allograft. The Polaris Spinal System is indicated for the following conditions: degenerative disc disease (defined as discogenic back pain with degeneration of the disc confirmed by history and radiographic studies), spondylolisthesis, trauma, (i.e., fracture or dislocation), deformity or curvature (i.e., scoliosis, kyphosis, Scheuermann's disease, and/or lordosis.), tumor, stenosis, pseudoarthrosis, or failed previous fusion.

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Prescription Use X (Part 21 CFR 801 Subpart D)	AND/OR	Over-The-Counter Use _____ (21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE OF NEEDED)

Concurrence of Center for Devices and Radiological Health (CDRH)

Ronald P. Jean -S

(Division Sign-Off)
Division of Orthopedic Devices
510(k) Number: K131615